

the change of address for the American Type Culture Collection. No new matter has been added.

Claims 17-18 have been amended and new claims 263-268 have been added, to more particularly point out and distinctly claim the subject matter Applicants regard as the invention. Support for the amendment to the claims and newly added claims is found throughout the specification as filed. No new matter has been added.

I. Miscellaneous

Priority

In compliance with 37 C.F.R. §1.78, Applicants have amended the first sentence of the specification to specifically refer to Provisional Application 60/029,960, to which the present application claims the benefit of priority.

II. Objections to the Specification

The Examiner objects to the specification, pointing out that the specification recites the old address of the American Type Culture Collection (ATCC). Applicants have amended the specification to include the new address of the ATCC. Accordingly, this objection has been obviated and should be withdrawn.

The Examiner also requests that Applicants correct any errors in the specification that Applicants are aware of. Applicants have reviewed the specification and have corrected any such errors that were identified during this review.

III. Objections to the Claims

The Examiner objects to claims 10 and 21, pointing out that both claims depend from canceled claims.

Applicants have canceled claims 10 and 21 without prejudice. Accordingly, these objections have been obviated and should be withdrawn.

IV. Rejections under 35 U.S.C. § 112, first paragraph

a. The Examiner appears to allege that access to the biological materials deposited in connection with the present application (i.e., ATCC Deposit No. 97755) is required for patentability of the claimed subject matter under 35 U.S.C. § 112.

Applicants disagree, and point out that the claims pending upon entry of the present amendment, do not specifically recite the deposited material. Applicants submit that the claims pending upon entry of the present amendment fully satisfy the requirements of 35 U.S.C. § 112 in the absence of access to the deposited material, and point out that procedures for making and using the polynucleotide and polypeptide sequences recited in the claims have been disclosed in the application or otherwise known in the art and can be carried out by one skilled in the art without undue experimentation.

In view of the foregoing, Applicants submit that the Examiner's rejection be reconsidered and withdrawn.

b. The Examiner has rejected claim 17, under 35 U.S.C. § 112, first paragraph, for lack of enablement. More particularly, the Examiner alleges:

while being enabling for a method of attenuating a *Streptococcus* infection, does not reasonably provide enablement for a method of preventing a *Streptococcus* infection.

Applicants disagree with this rejection and respectfully traverse.

Preliminarily, Applicants point out that claim 17 is not a member of the group of claims provisionally elected by Applicants in response to the Examiner's Restriction Requirement dated March 3, 1999 (Paper Number 9), now made final. Thus, claim 17 should properly have been withdrawn from consideration when the restriction requirement was made final. Accordingly, while Applicants submit that the subject matter of claim 17 (prior to amendment) is fully enabled by the specification as filed, Applicants will not make any substantive arguments in this application establishing the patentability of claim 17. Nonetheless, Applicants point out that claim 17 has been amended so as to delete the offending language. In view of the above, Applicants request that this rejection be reconsidered and withdrawn.

In view of the amendments and comments above, Applicants believe that the rejections under 35 U.S.C. § 112, first paragraph, have been overcome and respectfully request that the rejections be reconsidered and withdrawn.

V. Rejection Under 35 U.S.C. § 112, second paragraph

a. The Examiner has rejected claims 18, 21, 236 and 261 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. More particularly, the Examiner contends that:

[t]here is no correlation step that relates the detected hybridization (claim 18 or 236) or the detected of the antibody-antigen complex (claim 21 or 261) to the *Streptococcus* nucleic acids or the antibodies in a biological sample.

Applicants disagree.

Preliminarily, Applicants point out that claims 18, 21, 236 and 261 are not members of the group of claims provisionally elected by Applicants in response to the Examiner's Restriction Requirement dated March 3, 1999 (Paper Number 9), now made final. Thus, claims 18, 21, 236 and 261, should properly have been withdrawn from consideration when the restriction requirement was made final. Accordingly, while Applicants submit that the scope of claims 18, 21, 236 and 261, is clear to a hypothetical person possessing an ordinary level of skill in the art, Applicants will not make any substantive arguments in this application establishing the patentability of claims 18, 21, 236 and 261. Nonetheless, Applicants have amended claim 18 to recite that the hybridization detected according to this method is indicative of the presence of *Streptococcus* nucleic acids in the biological sample being assayed. Furthermore, Applicants have canceled claims 21, 236 and 261 without prejudice and reserve the right to pursue the subject matter of claims 21, 236 and 261 in one or more divisional applications. In view of the above, Applicants request that these rejections be reconsidered and withdrawn.

b. Further, the Examiner has rejected claims 11, 14, and 17-18, under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. More particularly, the Examiner contends that:

Claims 11 and 18 are vague in the recitation of "any of the polypeptides described in Table 1" (claim 11) and "one or more of the above-described nucleic acid probes" (claim 18). The claims do not recite the election of nucleic acid sequences encoding the polypeptide of SEQ ID NO:55 and/or 56.

Applicants traverse.

Preliminarily, Applicants point out that claims 11, 14, and 17-18, are not members of the group of claims provisionally elected by Applicants in response to the Examiner's

Restriction Requirement dated March 3, 1999 (Paper Number 9), now made final. Thus, claims 11, 14, and 17-18, should properly have been withdrawn from consideration when the restriction requirement was made final. Nonetheless, Applicants have amended claims 17 and 18 so as to delete the offending language. Additionally, Applicants have canceled claims 11 and 14, without prejudice and reserve the right to pursue the subject matter of claims 11 and 14, in one or more divisional applications. In view of the above, Applicants request that these rejections be reconsidered and withdrawn.

Applicants assert that in view of the above amendments and remarks, the Examiner's rejections under 35 U.S.C. § 112, second paragraph, should be reconsidered and withdrawn.

VI. Indication of Allowable Subject Matter

Applicants gratefully acknowledge the Examiner's statement that claims 198-235, 237-260 and 262 are free of prior art.

VII. Conclusion

Applicants respectfully request that the amendments and remarks of the present response be entered and made of record in the present application. The application is believed to be in condition for allowance. Early notice to that effect is earnestly solicited. If, in the opinion of the Examiner, a telephone conference would expedite prosecution, the undersigned can be reached at the telephone number indicated below. If a fee is required in

connection with this paper, please charge Deposit Account No. 08-3425 for the appropriate amount.

Respectfully submitted

Date: December 17, 1999


Kenley K. Hoover (Reg. No. 40,302)
Attorney for Applicants

Human Genome Sciences, Inc.
9410 Key West Avenue
Rockville, MD 20850
(301) 610-5771 (telephone)

KKH/ur